REMARKS

The office action has rejected claims 1-9 as being obvious in light of the Lee reference (US Patent No. 5,367,054) and the Ellis et al. article. As stated in the office action, "Given that Ellis et al teach using the anti-gliadin antibody containing composition for immunodetection and the teaching by Lee on the advantage of making IgY antibodies ie., that egg yolk is a very good source of specific antibodies and that the antibodies are more specific (see col. 1, lines 34-46), one of ordinary skill in the art would have been motivated to make the anti-gliadin antibodies for immunodetection as IgY antibodies for the high specificity offered by the egg yolk.

Applicants have claimed a composition for a particular therapeutic use, the entirety of which is not found in any of the cited references, taken singularly. It is true that egg yolk antibodies and IgY to a wide range of antigens were known. The Lee reference teaches a specific method of extracting and isolating IgY from egg yolks. However, the Lee reference is general to all antigens which may potentially result in immune egg yolks. There is specific reference only to anti-pathogenic immunoglobulins, such as anti-bacterial antibodies.

It is also true that IgG antibodies to gluten or gluten components was also known. Ellis *et al.* relates to an assay for detection of gluten in foods using a sandwich ELISA. Two types of IgG antibodies were necessary: a polyclonal antibody to gliadin used as a capture antibody, and a monoclonal antibody as a detection antibody. Ellis *et al.* has no teachings related to IgY or egg yolk antibodies.

It is respectfully submitted that a *prima facie* case of obviousness has not been made. The stated motivation to combine in the office action is that egg yolk antibodies are more specific. However, please note that the Lee reference states that this alleged advantage is merely possible - "These [advantages] include the potential of producing more specific antibodies against antigens in birds and mammals." (col. 1, lines 37-38.)

With respect to its combination of the Lee reference and the Ellis article, a person skilled in the art would only conclude that there is a possibility that IgY antibodies to gliadin may be more useful, but would certainly not be led to a conclusion of any certainty.

There are differences between IgY and IgG as a class which makes the claimed invention in the present case unpredictable. It is common general knowledge that IgY differs structurally from mammalian IgG, most importantly in the constant region. IgY is much less antigenic than IgG. In particular, as outlined in US Patent No. 4,550,019, the following differences are apparent:

(i) different amino acid compositions and sequences in the basic molecules,

(ii) different electrophoretic mobilities (IgY has much higher mobility than the corresponding mammalian serum IgG)

(iii) materially different isoelectric pH values, namely about 5.8 in the case of egg yolk gammaglobulin and about 6.8 in the case of mammalian serum IgG. This in turn is evidence of material difference in the ratios of carboxyl and amino groups (egg yolk gammaglobulin having relatively more of the former).

(iv) Different molecular weights, namely 175000 daltons in the case of egg yolk gammaglobulins as compared with 150000 daltons for mammalian IgG.

(v) Substantially different chemical stabilities, for which reason as stated above egg yolk gammaglobulins suffer severe damage when subjected to the conditions of most conventional purification processes which have been used successfully for IgG from mammals. Egg yolk gammaglobulin requires the presence of non-ionic surfactants as stabilisers in certain conditions where mammalian IgG is stable without such surfactant.

(vi) Ionic detergents inhibit the antigen-antibody reaction of mammalic IgG, but do not (at least not at modest concentrations) have an effect on the antibody-antigen reaction of egg yolk gammaglobulin.

(vii) Mammalian IgG remains in the monomeric form in low and high molar salt solution. IgY is monomeric in 0.15 molar NaCl and is dimeric in 1.5M NaCl.

Thus, the teachings of prior art related to IgG cannot be transferred without modification to procedures involving IgY. One cannot simply substitute IgY for IgG as these are not equivalent elements. Therefore, the present invention which is an antibody not previously described in the prior art, namely IgY specific to components of gluten, is not a predictable result of known components.

Furthermore, the stated motivation to combine Lee and Ellis, would be an attempt to solve a problem which does not exist. The stated motivation to combine is that IgY has the potential of providing more specific antibodies. While IgY antibodies may hold the potential of being more specific, the Ellis article describes a highly specific assay using polyclonal and monoclonal IgG antibodies to gliadin. The assay used antibodies specific enough to allow epitope identification and quantitation. The Ellis assay, using IgG, is a highly sensitive and highly specific assay for gliadin. There was no need or suggestion or motivation to attempt to find more specific antibodies. One skilled in the art would not look for teachings in an attempt to improve specificity. Furthermore, one skilled in the art would not necessarily look to the IgY art merely to chase some potential increase in specificity.

It is submitted that Applicant's claimed invention does not constitute a predictable use of prior art elements.

Lastly, claim 1 has been amended to recite the addition of a "physiologically suitable carrier, excipient or diluent". Neither Lee nor Ellis envision the use of IgY as a therapeutic agent, and do not disclose the use of a carrier, excipient or diluent for this purpose. In fact, Lee is directly solely to the isolation and purification of IgY. In the present invention, the egg yolk can be used whole as the therapeutic agent, with the egg yolk itself being the carrier. No purification is needed in this one embodiment.

New claim 14

Applicant submits new claim 14 in Jepson format. The preamble of a Jepson claim is presumed to be a substantive claim limitation. Therefore, the characterization of the composition as one for treating or ameliorating the symptoms of celiac disease is not merely a statement of intended use. It is a substantive limitation limiting claim scope. Accordingly, claim 14 is novel and inventive over the cited prior art.

The Ore Mune Magna Product

The supplier of the Ore Mune Magna product obtains their product from the Applicants. The first provision of the product to Ore Mune Magna was no earlier than May, 2006. The Applicant's are attempting to determine a precise date, but it is not earlier than May, 2006.

CONCLUSION

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance and passage to issuance is respectfully requested.

Respectfully submitted,

Sunwoo, Hoon and Sim, Jeong S.
By their Agent

Edward Yoo (Reg. No. 41,435)

CORRESPONDENCE ADDRESS CUSTOMER NO. 22828